UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

15 MAR 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Mole Med[tm] Castor Oil, EPA File Symbol 64439-R, Chem code # 031608, Data Waiver Request of January 6, 1993

FROM: Anthony F. Maciorowski, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

TO: Robert Forrest PM-14 & Daniel Peacock
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Mole Med castor oil was classified by the Agency as a biochemical pesticide in February 1992 for the following reasons:

1. The source of the castor oil is natural being from the beans of the castor-oil plant, *Ricinus communis*, native to India.

2. the castor oil is of food grade and

3. the mode of action is nontoxic.

The castor oil used as the active ingredient (A.I.) of Mole Med is U.S. Pharmacopeia (USP) grade refined to remove the characteristic odor and taste. Castor oil has a long history of medicinal use as a cathartic or laxative. Mole Med allegedly acts as a repellent because of possible irritant effects on moles according to the applicant.

The Tier 1 ecological effects data requirements of CFR 40 158.690, Table (d) Biochemical pesticides non-target organism and environmental data requirements are the following:

Kind of data required	Guideline reference No.
Avian acute oral, bobwhite quail	154-6/71-1
Avian dietary, bobwhite quail	154-7/71-2
Freshwater fish LC_{50}, rainbow trout	154-8/72-1
Freshwater invertebrate LC_{50}	154-9/72-2

Castor oil is currently being recommended for reduced data requirements by the Ad Hoc Screening Committee for Reduced Risk Pesticides consisting of representatives from the Health Effects Division, Environmental Fate and Effects Division, Registration Division and Special Review and Reregistratrion Division. Please see the attached memorandum from the Ad Hoc Screening Committee which recommends reduced data requirements for castor oil based on its meeting criteria listed in the June 1992 draft Guidance for Making Determinations to Reduce Data Requirements for certain pesticidal products. Pesticide products in this category would be exempt from the generic toxicology, ecological effects and environmental fate data requirements for the active ingredient as presently set forth in CFR 40 Part 158.

The registrant's representative submitted waiver requests on 01/06/93 for 154-6 Avian acute oral, 154-7 Avian dietary, 154-8 Freshwater fish LC_{50} and 154-9 Freshwater invertebrate LC_{50} data requirements. Adequate rationale was provided based on minimal exposure to birds, lack of rat oral toxicity, FDA approval as a food additive and medicine, low solubility and biodegradability of castor oil which is 87% ricinoleic acid.

In consideration that castor oil generally meets the criteria of the draft guidance for reduced data requirements and the data waiver request rationales submitted by the registrant, it is recommended that the nontarget organism data requirements be waived.

Since the registrant provided information that the solubility of castor oil has been tabulated at various levels between 100 and 300 mg/l, there is an undetermined possibility that some aquatic organisms may be adversely affected. To mitigate such risks, it is recommended that the label state:

ENVIRONMENTAL HAZARDS

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

Also, in the Mole Med labeling under directions for use, change: "Then water in for 25 minutes." to: "Then soak in with water in for about 25 minutes. Avoid using excess water that may flow off turf into streams, ponds, gutters or storm sewers."